

# Does ecabet sodium prevent low-dose aspirin-induced small intestinal mucosal injury?

<b>Submission date</b> 01/09/2018	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 01/10/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 10/01/2019	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Low doses of aspirin (LDA) are widely known to have blood clotting effects. However, aspirin does through through suppressing production of molecules called prostaglandins. The reduction in prostaglandins can lead to injury of the intestinal mucosa. Therefore, it is recommended that LDA users also use another type of drug called a proton pump inhibitor (PPI), which can help to prevent this mucosal injury in the upper gastrointestinal tract. PPIs inhibit secretion of stomach acid. However, the inhibition of stomach acid secretion does not prevent mucosal injuries in the small intestine as a result of LDA use. A strategy to prevent LDA-induced injuries in the small intestine has not yet been established. This study aims to investigate whether high doses of ecabet sodium (ES) can be used to prevent LDA-induced small intestinal mucosal injuries.

### Who can participate?

Healthy adults aged 20-65

### What does the study involve?

Participants will be randomly allocated to group A or group B. Group A will receive 100 mg of LDA to take once daily, whereas group B will receive 100 mg of LDA (once daily) and 4 g of ES (1 g taken 4 times daily). Both groups will be asked to take these for a 2 week period. Participants will undergo small bowel capsule endoscopy (SBCE) before beginning to take the study drugs and after taking the drugs for 2 weeks.

### What are the possible benefits and risks of participating?

There are no known benefits to participants taking part in this study. The possible risks of taking part in this study include adverse events associated with administration of LDA or ES, and retaining the capsule endoscope in the body.

### Where is the study run from?

Osaka Medical College Hospital (Japan)

### When is the study starting and how long is it expected to run for?

December 2009 to March 2012

Who is funding the study?  
Second Department of Internal Medicine, Osaka Medical College (Japan)

Who is the main contact?  
Kazuhiro Ota  
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## Contact information

**Type(s)**  
Public

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
UMIN000033984

## Study information

**Scientific Title**  
Preventive effect of ecabet sodium on low-dose aspirin-induced small intestinal mucosal injury: a randomised, double-blind, pilot study

**Study objectives**  
Ecabet sodium (ES), a gastric mucoprotective drug that locally acts as an antiulcer agent, has anti-pepsin activity. ES binds to proteins to form a complex that is resistant to the peptic activity of gastric juice, increasing the capacity of the gastric mucosa to synthesize prostaglandin E2 and/or prostacyclin and enhancing gastric mucosal defensive factors, such as mucosal blood flow, mucosal adherent mucus, and mucosal bicarbonate secretion. As these mechanisms share some features with those of rebamipide, we hypothesized that ES might also prevent small intestinal mucosal injury.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Review Committee at Osaka Medical College, 18/01/2010, No. 730

**Study design**

Interventional prospective double-blind pilot randomised controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Hospital

**Study type(s)**

Treatment

**Participant information sheet**

No participant information sheet available

**Health condition(s) or problem(s) studied**

Low-dose aspirin-induced small intestinal mucosal injury

**Interventions**

Participants were randomly allocated to group A and group B and instructed to take the study drug(s) orally for 2 weeks. A coordinator performed a simple fixed-allocation randomisation using a block-randomization scheme.

Group A received LDA (low-dose aspirin) (100 mg) to take once daily. Group B received LDA to take once daily and 4.0g of ecabet sodium (ES) (1.0 g to be taken 4 times daily, GASTROM® Granules 66.7%, Mitsubishi Tanabe Pharma Corporation, Osaka, Japan). The dosage of LDA for this group was determined on the basis of the dosage recommended for antithrombotic activity in cardiovascular and cerebrovascular diseases. Small bowel capsule endoscopy (SBCE) was performed before and 2 weeks after drug administration.

The total duration of treatment was determined based on previous reports on LDA-induced small intestinal mucosal injury.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Ecabet sodium Low-dose aspirin

**Primary outcome measure**

Comparison of the severity of small intestinal mucosal injury between baseline and 2 weeks after aspirin administration in each group. Small intestinal lesions were examined using a PillCamSB (Given Imaging, Ltd, Yoqneam, Israel), an SBCE device specifically designed for assessing the small intestine. The SBCE findings were evaluated to identify spotty redness, patchy redness, erosion, and ulcer. In addition, if bleeding or stenosis was detected, these findings were appended to those related to mucosal injuries. A spotty redness was defined as a point, a patchy redness as a red region with a border extending from the peripheral normal mucosa, an erosion as a defect in the normal villus mucosa, and an ulcer as defects covered with a white coat. Two investigators independently assessed the capsule endoscopic images under blinded conditions. If the observers recorded different findings, they discussed the case until an agreement was reached. This was assessed at the baseline and after 2 weeks.

### **Secondary outcome measures**

Comparison of the severity of small intestinal mucosal injury 2 weeks after aspirin administration between group A and group B, assessed as per primary outcome measure.

### **Overall study start date**

11/12/2009

### **Completion date**

31/03/2012

## **Eligibility**

### **Key inclusion criteria**

1. Healthy adults
2. Aged 20-65
3. Provided informed consent based on full understanding of the study protocol
4. No history of medication use during the month before enrolment in the study

### **Participant type(s)**

Healthy volunteer

### **Age group**

Adult

### **Sex**

Both

### **Target number of participants**

30

### **Key exclusion criteria**

1. History of peptic ulcers or gastrointestinal bleeding
2. Significant hepatic, renal, heart or respiratory diseases
3. History of gastrointestinal surgery other than appendectomy
4. Use of any of the following within 2 weeks prior to the study:
  - 4.1. Oral histamine H2-receptor antagonists
  - 4.2. Gastrointestinal kinetic agents
  - 4.3. Gastric mucoprotective drugs

5. Use of any of the following within 4 weeks prior to the study:
- 5.1. Oral non-steroidal anti-inflammatory drugs (NSAIDs)
  - 5.2. Steroids
  - 5.3. Anticholinergic drugs
  - 5.4. Anticancer drugs
  - 5.5. Antithrombotic drugs
6. Alcohol or chemical dependency
7. History of gastrointestinal obstruction
8. Refusal to consent to surgery that would be required if the capsule endoscope was retained in the body
9. Determination by the investigator, at his/her discretion, that the participant is ineligible for participation in the study for any reason

**Date of first enrolment**

04/10/2011

**Date of final enrolment**

28/12/2011

## **Locations**

**Countries of recruitment**

Japan

**Study participating centre**

**Osaka Medical College**

2-7, Daigaku-machi

Takatsuki

Japan

569-8686

## **Sponsor information**

**Organisation**

Osaka medical college

**Sponsor details**

2-7, Daigaku-machi

Takatsuki

Japan

569-8686

**Sponsor type**

University/education

**ROR**

## Funder(s)

### Funder type

Not defined

### Funder Name

Investigator initiated and funded

## Results and Publications

### Publication and dissemination plan

Planned publication in a high impact, peer-reviewed journal

### Intention to publish date

31/03/2013

### Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from clash\_kaz@yahoo.co.jp

### IPD sharing plan summary

Available on request

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	08/01/2019	10/01/2019	Yes	No